K041833

10/25/04

APPENDIX 7
510(k) Summary

DEC 1 0 2004

Consolidated Machine Corp.
76 Ashford St.
Boston, Ma. 02134
Tel: 617-782-6072
Fax: 617-787-5865

510K Summary of Safety and Effectiveness
June 4, 2004
Consolidated SSR and SR Series Steam Sterilizers

1. **Sponsor Name**
   Consolidated Machine Corp.
   76 Ashford St.
   Boston, Ma. 02134

2. **Device Name**
   Proprietary Name: Consolidated SSR Series and SR Series Sterilizers
   Models: SSR-2A, SSR-3A, and SR-24E
   Common Name: Steam Sterilizer or Autoclave
   Classification Name: Steam Sterilizer

3. **Identification of Legally Marketed Device**
   Getinge/Castle , "Castle Series 100HC", K994314

4. **Device Description**
   The Consolidated SR and SSR Series Sterilizers are for general purpose gravity or vacuum steam sterilization of heat and moisture-stabile goods, surgical instruments, and supplies. All models utilize both gravity/downward air displacement with positive pulse conditioning and pressure/vacuum pulsing for dynamic air removal. Up to 16 cycles can be easily accessed and are password protected. All cycle phases are sequenced and monitored by the Mark V control system, providing both audible and visual notification of deviation from certain operating parameters. These sterilizers can either be supplied for connection to direct building steam supply of 50-80 PSI of pressure or come equipped with an integral, electrically heated steam generator.

5. **Intended Use**
   Consolidated SSR/SR Series Steam Sterilizers are intended for use by health care facilities. They are to be used to sterilize wrapped and unwrapped surgical instruments, linens, and liquids (liquids not intended for direct patient contact) by means of pressurized steam.

6. Comparison of Technological Characteristics

The Consolidated SR and SSR Series Steam Sterilizers are substantially equivalent in design, materials, construction and intended use as those of the predicates identified above. Since the Consolidated SR and SSR Series Steam Sterilizers are the same in intended use and technological characteristics as the predicate devices, they do not raise any new safety and efficacy concerns when compared to these similar legally marketed devices.

7. Performance Testing

Biological and physical testing was conducted to determine device functionality and conformance to design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Arthur Trapotsis
Director, R & D
Consolidated Machine Corporation
P.O. Box 297
76 Ashford Street
Boston, Massachusetts 02134

DEC 10 2004

Re: K041833
Trade/Device Name: Consolidated SSR and SR MC-Series Steam Sterilizer,
Models: SSR-2A, SSR-3A, SR-24E
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: October 26, 2004
Received: October 27, 2004

Dear Mr. Trapotsis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

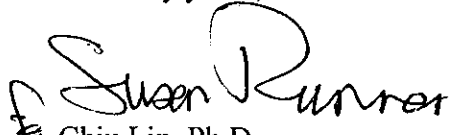
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDIICATION FOR USE STATEMENT

510(k) Number (if known): This submission K041833

Device Name: Consolidated SSR and SR MC-Series Steam Sterilizer

Models: SSR-2A, SSR-3A, SR-24E

Indications For Use:

Consolidated SSR and SR MC-Series Steam Sterilizers are intended for use by health care facilities. They are to be used to sterilize wrapped and unwrapped surgical instruments, linens, and liquids (liquids not intended for direct patient contact) by means of pressurized steam.

See attached for Load Specifications and Cycle Parameters.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M Chaudhry MD 12-10-04

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K041833